RH-I-4a 1/99

INSTRUCTIONS FOR PREPARATION OF FORM RH-F-4A

Item No.

1. Self Explanatory

2. Self Explanatory

3. State Regulations provide that the using physician have substantial experience in the proposed use, the handling and administration of radioisotopes, and, where applicable, the clinical management of radioactive patients. The physician must furnish suitable evidence of such experience with his application. Supplement A-Human Use, Page2, is provided for conveniently presenting these details.

4. Name or describe each clinical use for each radioisotope and chemical form administered. List radiological protection procedures to be followed in sufficient detail to permit a realistic evaluation of the potential radiological hazards.

5. (a) Dosage for treatment of patient will depend upon the clinical judgement of the responsible physician; the Agency is only interested in the proposed dosage range. (b) For experimental programs, or new and unusual uses, the maximum single dose of radioactive material to be administered should be included and the approximate number and frequency of such doses. Rationale for unusual high dosages should be presented. The proposed use should be outlined in detail demonstrating that radiological health and safety of the patient will not be jeopardized. If the use duplicates, or is based on, a use reported in the technical literature, an abstract of such a report or article and a brief statement as to how such use will be followed or modified will surface.

6. Radioisotopes furnished by N.R.C. facilities are pharmaceutically UNREFINED. An applicant should include information regarding the processing or standardization procedure if radioactive material will not be obtained in precalibrated form for oral administration or precalibrated and sterilized form for parenteral administration.

7. Self-explanatory.

8. (a) Give the name(s) and address(es) of the hospital(s) which will admit your patients that have been administered radioisotopes. (b) Submit a copy of the radiological protection instructions furnished to the hospital personnel regarding the care of patients to whom radioisotopes have been administered. Attach a list of radiation instruments you will make available to the hospital.

9. To be completed by using physician.

10-11. It is recommended that these items be completed by the applicant physician's preceptor in the use of radioisotopes.

12. The pre-septoring physician is usually the chairman of the medical isotopes committee of the Institution where clinical experience was acquired. However, the preceptor may be a staff physician experienced in the clinical use of radioisotopes under whom the using physician's radioisotope training and experience was acquired. If possible, the physician's entire clinical radioisotope experience should be included. Additional comments may be presented on supplemental sheets which should include the applicant's name and address and the item number to which the supplemental information applies on such sheet.

Note – For Medical Institutional Type Program

1. List the names, specialties, and radioisotopes experience, if any, of each member of the local isotope Committee.

2. State the procedures the local isotope committee will use to control the procurement and to approve uses of radioisotopes at the institution.

3. Submit a copy of instructions given to nurses who will care for patients containing radioactive material.

4. Submit a copy of radiological protection rules and procedures to individuals using radioisotopes at the institution.